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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

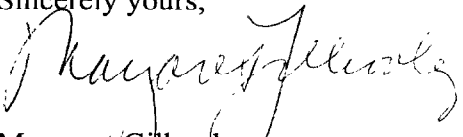
Docket Number 02N-0209- Request for Comments on First Amendment Issues:
Supplementary Comment on DTC Ads

This letter supplements my July 24, 2002 response to the Notice published by the Food and Drug Administration (FDA) on May 16, 2002 in 67 Federal Register 34942 which requested comments to ensure that the agency's regulations and policies "continue to comply with the governing First Amendment case law."

With respect to DTC ads, FDA asked if the DTC ads lead to over-prescription, if they encourage treatment for under-diagnosed diseases, and if they create any impediments to the ability of doctors to give optimal medical advice. In my July 24 response I recommend that the DTC ads state prominently that consumers need to "Consult your doctor about the range of treatment choice that may be available."

I now believe that this disclosure should be explicit about the factors on which the doctor gives advice, as discussed in my earlier response. Thus, the disclosure should state "Consult your doctor about the range of treatment choice that may be available, and their risks, benefits and costs." Providing this disclosure will prevent consumers from being misled by the single-drug focus of the ads about the range of factors that affect the drug choice and the physician's advice. Consequently, the disclosure is appropriate under FDA's authority to prevent misleading labeling.

Sincerely yours,


Margaret Gilhooly
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